



General

Guideline Title

Abiraterone for treating metastatic hormone-relapsed prostate cancer before chemotherapy is indicated.

Bibliographic Source(s)

National Institute for Health and Care Excellence (NICE). Abiraterone for treating metastatic hormone-relapsed prostate cancer before chemotherapy is indicated. London (UK): National Institute for Health and Care Excellence (NICE); 2016 Apr 27. 48 p. (Technology appraisal guidance; no. 387).

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Recommendations

Major Recommendations

Abiraterone in combination with prednisone or prednisolone is recommended, within its marketing authorisation, as an option for treating metastatic hormone-relapsed prostate cancer:

- In people who have no or mild symptoms after androgen deprivation therapy (ADT) has failed, and before chemotherapy is indicated
- Only when the company rebates the drug cost of abiraterone from the 11th month until the end of treatment for people who remain on treatment for more than 10 months.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Metastatic hormone-relapsed prostate cancer

Guideline Category

Assessment of Therapeutic Effectiveness

Treatment

Clinical Specialty

Internal Medicine

Oncology

Urology

Intended Users

Advanced Practice Nurses

Nurses

Physician Assistants

Physicians

Guideline Objective(s)

To evaluate the clinical effectiveness and cost-effectiveness of abiraterone for treating metastatic hormone-relapsed prostate cancer before chemotherapy is indicated

Target Population

Adult men with metastatic hormone-relapsed prostate cancer who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy (ADT) in whom chemotherapy is not yet clinically indicated

Interventions and Practices Considered

Abiraterone in combination with prednisone or prednisolone

Major Outcomes Considered

- Clinical effectiveness
 - Overall survival (OS)
 - Radiographic progression-free survival (rPFS)
 - Time to opiate use for cancer pain
 - Time to initiation of cytotoxic chemotherapy
 - Time to deterioration in Eastern Cooperative Oncology Group Performance Status (ECOG PS) by ≥ 1 point
 - Time to prostate-specific antigen (PSA) progression
 - PSA response rate
 - Objective response rate in patients with measurable disease
 - Duration of response
 - Quality of life (QoL) total score and each subscale (health-related quality of life [HRQL] as measured by the Functional Assessment of Cancer Therapy – Prostate [FACT-P] instrument
 - Time to pain progression

- Time to analgesic progression
- Adverse effects of treatment
- Cost-effectiveness

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Care Excellence (NICE) commissioned an independent academic centre to perform an assessment of the manufacturer's submission on the technology considered in this appraisal and prepare an Evidence Review Group (ERG) report. The ERG report for this appraisal was prepared by Kleijnen Systematic Reviews Ltd in collaboration with Erasmus University Rotterdam and Maastricht University (see the "Availability of Companion Documents" field).

Clinical Effectiveness

Critique of the Methods of Review(s)

Searches

Searches were reported for all databases required by NICE guidance: Medline, Medline In-Process, EMBASE and the Cochrane Library. The database provider for each database was listed; the date span of the databases searched and the specific date the searches were run on were provided. The manufacturer additionally searched conference proceedings for specific conferences in specific years.

The manufacturer reported that the searches were an update of previous searching undertaken to support an earlier submission relating to NICE TA259: abiraterone in metastatic castration-resistant prostate cancer (mCRPC) after docetaxel. The search strategies used for the earlier submission were not amended, as the study population (men with prostate cancer) and interventions included (standard of care in England and Wales, and investigational interventions) were appropriate for this submission.

The manufacturer translated the research question into appropriate search strategies and the ERG considered the searches to be adequate. Searches were clearly structured and divided into population and intervention facets. Study design limits to identify randomised controlled trials (RCTs) and non-RCTs were applied, and the manufacturer stated that the search strategies for clinical effectiveness were used for the non-RCT evidence and adverse events sections of the submission. The study design filters were not referenced, so it was unclear whether the filters used were published objectively derived filters. The filters contained a combination of subject heading terms and free text terms and the ERG deemed them to be adequate. In response to the ERG points of clarification (POC) letter, the manufacturer reported that the RCT and non-RCT (observational) search filters used in the current submission were based on those provided by the Scottish Intercollegiate Guidelines Network (SIGN).

The ERG noted that the manufacturer searched EMBASE and Medline simultaneously using a single database provider (embase.com) and search strategy. This has limitations when using subject heading terms which could affect recall of results. EMBASE subject heading terms (Entree) were used in the search strategy, and although simultaneous searching of embase.com should automatically identify and search for equivalent Medline subject heading terms (MeSH), it is not clear if this is the case for all potentially useful MeSH terms. Given the potential limitations of this approach, the ERG considered it preferable to search each database separately, or at least to ensure inclusion of both Entree and MeSH terms in the search strategy.

Indirect and Mixed Treatment Comparisons

Searches were not carried out as no indirect or mixed treatment comparisons were performed.

Non-RCT Evidence

The same search strategies and databases used for the clinical evidence section of the submission were used for non-RCT evidence. The search strategies included a study design filter for non-RCTs.

Adverse Events

The same search strategies and databases used for the clinical evidence were used to identify adverse events data. Centre for Reviews and Dissemination (CRD) guidance recommends that if searches have been limited by an RCT filter, additional searches should be undertaken to ensure that adverse events that are long-term, rare or unanticipated are not missed. Despite the addition of a non-RCT filter the ERG considered that it was possible that some relevant evidence may not have been identified as a consequence of the study design limits.

Cost-effectiveness

Searches were carried out for all of the databases required by NICE: Medline, Medline In-Process, EMBASE, National Health Service Economic Evaluation Database (NHS EED) and EconLit. The database provider for each database was reported; the date span of the databases searched and the specific date the searches were run were provided. The manufacturer additionally searched conference proceedings, and health technology assessment organisation websites.

As with the clinical effectiveness searches, this was an update of previous searches undertaken to support an earlier submission relating to NICE TA259: abiraterone in mCRPC after docetaxel. The search strategies used for the earlier submission were not amended, as the study population (men with prostate cancer) and interventions included (standard of care in England and Wales, and investigational interventions) were appropriate for this submission.

The manufacturer translated the research question into appropriate search strategies and the ERG considered the searches to be adequate. Searches were clearly structured and divided into population and intervention facets. A study design filter to identify cost-effectiveness studies was applied and the manufacturer stated that this was based on standard filters developed by SIGN.

Summary of Searching

The searches in the manufacturer's submission were, in the main, well documented, clearly presented and reproducible. Search strategies did not report the number of records retrieved by each line or for each database. Inclusion of this information would have aided the ERG in assessment of the searches, making it easier to see where errors might have occurred, what impact amendments made to the strategies, and to ensure that the methods were transparent.

See Section 4.1 of the ERG report for more information on critique of the methods of review.

Inclusion Criteria

The updated review for this submission utilised a broad set of inclusion criteria (see Table 4.1 in the ERG report) and included all studies in mCRPC.

One RCT was included in the review.

Cost-effectiveness

The quality of the search strategy is discussed above.

Inclusion/Exclusion Criteria Used in the Study Selection

The inclusion criteria were reported in a table in the manufacturer's submission. Those that did not meet the eligibility criteria were excluded. See Table 5.1 in the ERG report.

ERG comment: The ERG considers that the inclusion and exclusion criteria used in the study selection are appropriate.

Included/Excluded Studies in the Cost-effectiveness Review

The systematic literature review identified 45 economic evaluations and 12 additional economic evaluations associated with Health Technology Assessment (HTA) appraisals.

ERG comment: None of these studies investigated abiraterone acetate plus prednisone/prednisolone (AAP) for the treatment of adult men who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy (ADT) and in whom chemotherapy is not yet clinically indicated and therefore their findings are less relevant to the current submission. For this reason the manufacturer has provided a de novo analysis. The ERG agrees with this approach.

Number of Source Documents

Clinical Effectiveness

One randomised controlled trial (RCT) was included, the COU-AA-302 trial.

Cost-effectiveness

- The systematic literature review identified 45 economic evaluations and 12 additional economic evaluations associated with health technology assessment (HTA) appraisals. However, none of these studies investigated abiraterone acetate plus prednisone/prednisolone (AAP) for the treatment of adult men who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy (ADT) and in whom chemotherapy is not yet clinically indicated and therefore their findings are less relevant to the current submission.
- The manufacturer presented an economic model.

See also Figure 2 of the manufacturer's submission (see the "Availability of Companion Documents" field) for the consort flow of systematic review to identify abiraterone acetate (AA) and comparator clinical trials and non-RCT studies.

Methods Used to Assess the Quality and Strength of the Evidence

Expert Consensus

Rating Scheme for the Strength of the Evidence

Not applicable

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Care Excellence (NICE) commissioned an independent academic centre to perform an assessment of the manufacturer's submission on the technology considered in this appraisal and prepare an Evidence Review Group (ERG) report. The ERG report for this appraisal was prepared by Kleijnen Systematic Reviews Ltd in collaboration with Erasmus University Rotterdam and Maastricht University (see the "Availability of Companion Documents" field).

Clinical Effectiveness

Critique of the Methods of Review(s)

Critique of Data Extraction

One randomised controlled trial (RCT) was included, the COU-AA-302 trial. The most recent data from this trial (third interim analysis) were extracted from the updated clinical study report, a review article and conference abstracts. The only full journal publication for the trial was based on the second interim analysis.

Quality Assessment

The quality assessments of the COU-AA-302 trial can be found in Appendix 3, Section 10.3 of the manufacturer's submission, and in Table 4.3 in the ERG report. The methods used to generate random allocation sequence and for concealment of allocation sequence were reported and were judged as adequate. Blinding status was clear and the study did not show any evidence of selective reporting. Overall, the COU-AA-302 trial was rated as being at a low risk of bias.

ERG Comment: The ERG agrees with the manufacturer's assessment on most items. Refer to Section 4.1.4 in the ERG report for areas of

disagreement.

Evidence Synthesis

No evidence synthesis is included in the submission. Docetaxel was considered not appropriate as a comparator by the manufacturer. The remaining comparator, best supportive care (BSC, prednisone or prednisolone), was included in the trial.

ERG comment: The ERG agrees that for the comparison of abiraterone acetate in combination with prednisolone versus BSC in adults with metastatic castration-resistant prostate cancer (mCRPC) who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy (ADT) in whom chemotherapy is not yet clinically indicated, the COU-AA-302 trial is most likely the best source of clinical effectiveness evidence.

See Section 4 of the ERG report for additional information on clinical effectiveness analysis.

Cost-effectiveness

Summary and Critique of Manufacturer's Submitted Economic Evaluation by the ERG

Model Structure

The model consisted of a discrete event simulation (DES) evaluating the cost-effectiveness of abiraterone acetate plus prednisone/prednisolone (AAP) in comparison to BSC (placebo plus prednisone/prednisolone [PP]) in adult men with mCRPC who were asymptomatic or mildly symptomatic after failure of ADT in whom chemotherapy was not yet clinically indicated. The approach allowed for tracking patients and their experiences at the individual level. The comparator, BSC (PP), was a proxy for an active monitoring strategy based on the PP group in the COU-AA-302 trial.

Patients diagnosed with asymptomatic or mildly symptomatic mCRPC post-ADT entered the model and were assigned to one of the two treatment pathways (BSC and AAP) as shown in Figure 5.1 of the ERG report. Patients for whom pre-docetaxel treatment was discontinued or in whom disease was progressed were monitored in a BSC (pre-docetaxel) phase prior to commencing docetaxel treatment. They started docetaxel only if Eastern Cooperative Oncology Group Performance status (ECOG PS) <2 (corresponding to Karnofsky PS $\geq 60\%$).

After docetaxel treatment was completed, patients were again monitored for disease progression and other active treatment (AAP) was given if benefits outweigh the risks. In this submission, the predicted use of post-docetaxel treatment was restricted to BSC and based on the observations from the COU-AA-302 trial. Furthermore it was assumed that if patients received AAP prior to docetaxel they would not be eligible for AAP retreatment post-docetaxel, whereas BSC patients were allowed to receive AAP post-docetaxel. Throughout the model, patients may receive additional treatments, but these are not expected to impact survival (i.e., no evidence exists demonstrating a statistically significant impact on survival) and are not explicitly considered in the model.

In the model structure different types of BSC can be distinguished:

- BSC (PP), active monitoring comparator treatment arm where patients are not receiving active treatments such as AAP before docetaxel that impact survival
- BSC (pre-docetaxel/post-docetaxel), time before receiving an active treatment that has shown to impact overall survival where patients are still receiving treatments that palliate symptoms (e.g., corticosteroids) of disease. This phase aimed to capture the slow progression of the disease during which time patients received treatments to alleviate worsening symptoms.
- BSC before death involves palliative care, until death. This consists of the "end of life" phase where patients are near death and will not receive additional active treatments that may impact survival, but instead are managed for their pain or other symptoms.

Figure 5.2 in the ERG report shows patient flow through model simulation.

ERG comment: While the manufacturer considers the model presented as "a simple discrete event simulation (DES) model," the ERG does not believe that a DES model, simulating individual patients using 17 prediction equations would have been the simplest and most transparent approach. The ERG believes instead that it would have been possible to use a more transparent model, for instance, a Markov model consisting of health states according to the treatment phases included in the current model and a sufficiently short cycle time. This model would also allow reflection of the clinical pathways in the UK and to produce results for subgroups with varying baseline characteristics. Also, the ERG is not convinced by the manufacturer's arguments that a patient level simulation would be necessary for the decision problem defined during the scope. It should be noted that acknowledging patient heterogeneity does not necessarily require patient level simulation. Transparency is a key aspect of modelling and in this specific case a more transparent model would be more convenient for an external reviewer to assess face validity and internal validity of the model.

See Section 5.2 of the ERG report for additional information on model structure and ERG comments. See Section 5 of the ERG report for more information on cost-effectiveness analysis.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Considerations

Technology appraisal recommendations are based on a review of clinical and economic evidence.

Technology Appraisal Process

The National Institute for Health and Care Excellence (NICE) invites 'consultee' and 'commentator' organisations to take part in the appraisal process. Consultee organisations include national groups representing patients and carers, the bodies representing health professionals, and the manufacturers of the technology under review. Consultees are invited to submit evidence during the appraisal and to comment on the appraisal documents.

Commentator organisations include manufacturers of the products with which the technology is being compared, the National Health Service (NHS) Quality Improvement Scotland and research groups working in the area. They can comment on the evidence and other documents but are not asked to submit evidence themselves.

NICE then commissions an independent academic centre to review published evidence on the technology and prepare an 'assessment report'. Consultees and commentators are invited to comment on the report. The assessment report and the comments on it are then drawn together in a document called the evaluation report.

An independent Appraisal Committee then considers the evaluation report. It holds a meeting where it hears direct, spoken evidence from nominated clinical experts, patients and carers. The Committee uses all the evidence to make its first recommendations, in a document called the Appraisal Consultation Document (ACD). NICE sends all the consultees and commentators a copy of this document and posts it on the NICE Web site. Further comments are invited from everyone taking part.

When the Committee meets again it considers any comments submitted on the ACD; then it prepares its final recommendations in a document called the Final Appraisal Determination (FAD). This is submitted to NICE for approval.

Consultees have a chance to appeal against the final recommendations in the FAD. If there are no appeals, the final recommendations become the basis of the guidance that NICE issues.

Who Is on the Appraisal Committee?

NICE technology appraisal recommendations are prepared by an independent committee. This includes health professionals working in the NHS and people who are familiar with the issues affecting patients and carers. Although the Appraisal Committee seeks the views of organisations representing health professionals, patients, carers, manufacturers and government, its advice is independent of any vested interests.

Rating Scheme for the Strength of the Recommendations

Not applicable

Cost Analysis

Summary of Appraisal Committee's Key Conclusions

Availability and Nature of Evidence

The company developed a discrete event simulation (DES) model because it allowed the flexibility to include a sequence of treatments, and to

model response to treatments that depend on previous treatments.

Uncertainties Around and Plausibility of Assumptions and Inputs in the Economic Model

The company's model was complex and lacked transparency, which made it difficult for the evidence review group (ERG) to validate and critique it.

In the model, data needed to be extrapolated beyond the period of the follow-up from COU-AA-302. The choice of extrapolation distribution affected the estimated duration of first treatment, which was a driver of the incremental cost-effectiveness ratio (ICER). To support its choice of a log-logistic extrapolation, the company provided data from: the final trial analysis; UK clinical practice; and US clinical practice. The committee concluded that its preferred analysis used either a log-logistic curve or a piecewise curve to predict time on first treatment.

Incorporation of Health-related Quality-of-Life Benefits and Utility Values. Have Any Potential Significant and Substantial Health-Related Benefits Been Identified That Were Not Included in the Economic Model, and How Have They Been Considered?

The company's model used utility values from the trial (Functional Assessment of Cancer Therapy [prostate cancer subscale] mapped to European Quality of Life-5 Dimensions [EQ-5D]), a survey and the literature. The model included a utility increment associated with taking abiraterone. Overall, the committee concluded that the company's modelled utility values were plausible.

The committee agreed that the benefit of delaying chemotherapy perceived by patients may not have been fully captured by the utility values included in the modelling and that accounting for this would have reduced the ICER.

Are There Specific Groups of People for Whom the Technology Is Particularly Cost Effective?

None were identified.

What Are the Key Drivers of Cost-effectiveness?

Using a Weibull or piecewise distribution instead of a log-logistic distribution for predicting time on first treatment increased the ICER.

The choice of trial population used to inform the model: the company's model used results from the subgroup of 902 people in COU-AA-302 for whom complete data were available on baseline characteristics. The ERG's exploratory base case used the intention-to-treat (ITT) population instead, and this increased the ICER. The committee agreed that, as a general principle, it preferred to use the ITT population for modelling because this reduces the risk of bias. However, in this specific case, the committee agreed with the company that using the full covariate subgroup provided a closer fit to the trial data. Accordingly, the committee preferred to use the full covariate subgroup.

Most Likely Cost-effectiveness Estimate (Given as an ICER)

The committee concluded that the ICER was likely to lie between £28,600 and £32,800 per quality-adjusted life year (QALY) gained.

Method of Guideline Validation

External Peer Review

Description of Method of Guideline Validation

Consultee organisations from the following groups were invited to comment on the draft scope, Assessment Report and the Appraisal Consultation Document (ACD) and were provided with the opportunity to appeal against the Final Appraisal Determination (FAD).

- Manufacturer/sponsors
- Professional/specialist and patient/carer groups
- Commentator organisations (without the right of appeal)

In addition, individuals selected from clinical expert and patient advocate nominations from the professional/specialist and patient/carer groups were also invited to comment on the ACD.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of evidence supporting the recommendations is not specifically stated.

The Appraisal Committee considered clinical and cost-effectiveness evidence submitted by the manufacturer of abiraterone and a review of this submission by the Evidence Review Group (ERG). The main clinical effectiveness evidence came from one randomised controlled trial (RCT). For cost-effectiveness, the Appraisal Committee considered an economic model submitted by the manufacturer.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate use of abiraterone for treating metastatic hormone-relapsed prostate cancer before chemotherapy is indicated

Potential Harms

The summary of product characteristics lists the following adverse reactions for abiraterone as being very common (that is, occurring in 1 in 10 or more people): diarrhoea, urinary tract infection, hypokalaemia (low blood potassium concentrations), hypertension (high blood pressure) and peripheral oedema (swelling of the limbs). The summary of product characteristics states that 'other important adverse reactions' are cardiac disorders, hepatotoxicity and fractures.

For full details of adverse reactions and contraindications, see the summary of product characteristics.

Contraindications

Contraindications

For full details of adverse reactions and contraindications, see the summary of product characteristics.

Qualifying Statements

Qualifying Statements

- The recommendations in this guidance represent the view of the National Institute for Health and Care Excellence (NICE), arrived at after careful consideration of the evidence available. When exercising their judgement, health professionals are expected to take this guidance fully into account, alongside the individual needs, preferences and values of their patients. The application of the recommendations in this guidance are at the discretion of health professionals and their individual patients and do not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or their carer or guardian.
- Commissioners and/or providers have a responsibility to provide the funding required to enable the guidance to be applied when individual health professionals and their patients wish to use it, in accordance with the National Health Service (NHS) Constitution. They should do so in light of their duties to have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities.

Implementation of the Guideline

Description of Implementation Strategy

- Section 7(6) of the [National Institute for Health and Care Excellence \(NICE\) \(Constitution and Functions\) and the Health and Social Care Information Centre \(Functions\) Regulations 2013](#) requires clinical commissioning groups, National Health Services (NHS) England and, with respect to their public health functions, local authorities to comply with the recommendations in this appraisal within 3 months of its date of publication.
- The Welsh Assembly Minister for Health and Social Services has issued directions to the NHS in Wales on implementing NICE technology appraisal guidance. When a NICE technology appraisal recommends the use of a drug or treatment, or other technology, the NHS in Wales must usually provide funding and resources for it within 3 months of the guidance being published.
- When NICE recommends a treatment 'as an option', the NHS must make sure it is available within the period set out in the paragraphs above. This means that, if a patient has metastatic hormone-relapsed prostate cancer (and has no or mild symptoms after androgen deprivation therapy has failed and in whom chemotherapy is not yet clinically indicated), and the doctor responsible for their care thinks that abiraterone is the right treatment, it should be available for use, in line with NICE's recommendations.
- NHS England and Janssen have agreed that abiraterone will be available to the NHS with a commercial access arrangement. The details of this commercial access arrangement are confidential. It is the responsibility of the company to communicate the details of the commercial access arrangement with the relevant NHS organisations. Any enquiries from NHS organisations about the commercial access arrangement should be directed to Janssen's customer services team on 01494 567 400 or janssenukcustomerservices@its.jnj.com.

Implementation Tools

Foreign Language Translations

Mobile Device Resources

Patient Resources

Resources

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

National Institute for Health and Care Excellence (NICE). Abiraterone for treating metastatic hormone-relapsed prostate cancer before chemotherapy is indicated. London (UK): National Institute for Health and Care Excellence (NICE); 2016 Apr 27. 48 p. (Technology appraisal guidance; no. 387).

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2016 Apr 27

Guideline Developer(s)

National Institute for Health and Care Excellence (NICE) - National Government Agency [Non-U.S.]

Source(s) of Funding

National Institute for Health and Care Excellence (NICE)

Guideline Committee

Appraisal Committee

Composition of Group That Authored the Guideline

Appraisal Committee Members: Dr Amanda Adler (*Chair*), Consultant Physician, Addenbrooke's Hospital Cambridge; Professor Ken Stein (*Vice Chair*), Professor of Public Health, University of Exeter Medical School; Dr Ray Armstrong, Consultant Rheumatologist, Southampton General Hospital; Dr Jeff Aronson, Reader in Clinical Pharmacology, University Department of Primary Health Care, University of Oxford; Professor John Cairns, Professor of Health Economics Public Health and Policy, London School of Hygiene and Tropical Medicine; Dr Lisa Cooper, Echocardiographer, Stockport NHS Foundation Trust; Mr Robert Hinchliffe, Clinical Senior Lecturer (Higher Education Funding Council for England; HEFCE) in Vascular Surgery and Honorary Consultant Vascular Surgeon, St George's Vascular Institute; Mrs Anne Joshua, Pharmaceutical Advisor NHS 111/NHS Pathways; Dr Miriam McCarthy, Consultant, Public Health, Public Health Agency, Northern Ireland; Professor Ruairidh Milne, Director of Strategy and Development and Director for Public Health Research at the National Institute for Health Research (NIHR) Evaluation, Trials and Studies Coordinating Centre at the University of Southampton; Dr Peter Norrie, Principal Lecturer in Nursing, DeMontfort University; Mr Christopher O'Regan, Head of Health Technology Assessment and Outcomes Research, Merck Sharp & Dohme; Dr Sanjeev Patel, Consultant Physician and Senior Lecturer in Rheumatology, St Helier University Hospital; Dr John Pounsford, Consultant Physician, Frenchay Hospital, Bristol; Dr Danielle Preedy, Lay member; Mr Alun Roebuck, Consultant Nurse in Critical and Acute Care, United Lincolnshire NHS Trust; Mr Cliff Snelling, Lay member; Professor Andrew Stevens, Professor of Public Health, Department of Public Health and Epidemiology, University of Birmingham; Mr David Thomson, Lay member; Dr Nicky Welton, Senior Lecturer in Biostatistics/Health Technology Assessment, University of Bristol; Dr Nerys Woolacott, Senior Research Fellow, Centre for Health Economics, University of York

Financial Disclosures/Conflicts of Interest

Committee members are asked to declare any interests in the technology to be appraised. If it is considered there is a conflict of interest, the member is excluded from participating further in that appraisal.

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Available from the [National Institute for Health and Care Excellence \(NICE\) Web site](#) . Also available for download in ePub and eBook formats from the [NICE Web site](#) .

Availability of Companion Documents

The following are available:

- Abiraterone for treating metastatic hormone-relapsed prostate cancer before chemotherapy is indicated. Resource impact report. London (UK): National Institute for Health and Care Excellence (NICE); 2016 Apr. 8 p. (Technology appraisal guidance; no. 387). Available from the [National Institute for Health and Care Excellence \(NICE\) Web site](#) .
- Abiraterone for treating metastatic hormone-relapsed prostate cancer before chemotherapy is indicated. Resource impact template. London (UK): National Institute for Health and Care Excellence (NICE); 2016 Apr. (Technology appraisal guidance; no. 387). Available from the [NICE Web site](#) .
- Riemsma R, Ramaekers B, Tomini F, Wolff R, van Asselt T, Joore M, Deshpande S, Worthy G, Duffy S, Armstrong N, Severens JL, Kleijnen J. Abiraterone for the treatment of chemotherapy naïve metastatic castration-resistant prostate cancer: a single technology appraisal. York (UK): Kleijnen Systematic Reviews Ltd; 2014. 129 p. Available from the [NICE Web site](#) .
- Abiraterone acetate (Zytiga®) for the treatment of metastatic castration-resistant prostate cancer in men not previously treated with chemotherapy. Single technology appraisal (STA). London (UK): National Institute for Health and Care Excellence (NICE); 2014 Feb. 308 p. Available from the [NICE Web site](#) .

Patient Resources

The following is available:

- Abiraterone for treating metastatic hormone-relapsed prostate cancer before chemotherapy is indicated. Information for the public. London (UK): National Institute for Health and are Excellence (NICE); 2016 Apr. 3 p. (Technology appraisal guidance; no. 387). Available in [English](#) and [Welsh](#) from the National Institute for Health and are Excellence (NICE) Web site. Also available for download in ePub and eBook formats from the [NICE Web site](#) .

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

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